IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/669,450	Confirmation No.: 4574
Applicant(s):	Mangiardi et al.	
Filed:	September 24, 2003	
Art Unit:	3734	
Examiner:	Kevin Thao Truong	
Title:	COATED STENT WITH GEOMETRY DETERMINED FUNCTIONALITY AND METHOD OF MAKING THE SAME	

Docket No.: 047956/288218
Customer No.: 37305

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APPEAL BRIEF TRANSMITTAL
(PATENT APPLICATION – 37 C.F.R. § 41.37)

1. Transmitted herewith is the APPEAL BRIEF in this application, with respect to the Notice of Appeal filed on April 3, 2009.

2. ☐ Applicant claims small entity status.

3. Pursuant to 37 C.F.R. § 41.20(b)(2), the fee for filing the Appeal Brief is:
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APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed April 3, 2009.

1. ***Real Party in Interest.***

The real party in interest in this appeal is Merit Medical Systems, Inc.

2. ***Related Appeals and Interferences.***

None.

3. ***Status of Claims.***

The present appeal involves Claims 1-49, wherein Claims 45-49 have been withdrawn from consideration. Claims 1-44 are under final rejection as set forth by the Office Action mailed November 4, 2008. The claims at issue are set forth in the attached Claims Appendix.

4. ***Status of Amendments.***

Claims 1-49 have not been amended following the final Office Action mailed November 4, 2008.

5. ***Summary of Claimed Subject Matter.***

Independent Claim 1 is directed to a medical appliance for placement within a portion of the anatomy of a patient (see p. 4, lines 17-19; p. 6, line 23 – p. 7, line 1). Claim 1 recites that the appliance includes a scaffolding configured to define a substantially cylindrical member having a distal end and a proximal end and a lumen extending longitudinally therebetween and therethrough (see FIGS. 1-3; p. 7, lines 3-13; p. 8, lines 23-29). Claim 1 also recites that along the longitudinal extension of the appliance the scaffolding has an interior and an exterior surface comprising struts (see FIGS. 1-3; p. 7, lines 3-13; p. 8, lines 23-29).

Moreover, independent Claim 1 recites that the appliance includes a coating coupled with the scaffolding such that the exterior surface of the scaffolding is raised with respect to the coating extending substantially over an area between the struts of the scaffolding (see FIGS. 1-3; p. 6, lines 3-10; p. 14, lines 13-16; p. 15, line 6 – p. 16, line 4).

6. ***Grounds of Rejection to be Reviewed on Appeal.***

Claims 1-44 stand rejected under under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,699,278 to Fischell et al. ("Fischell").

7. ***Argument.***

Initially, Applicants note that in the final Official Action, the Examiner has failed to provide Applicants with a sufficient claim construction or interpretation of the cited reference so as to enable the Applicants to effectively formulate a response. *See* MPEP §§706, 706.07. In this regard, as has been recognized by the Board of Patent Appeals and Interferences (BPAI), "The Examiner must make specific findings as to claim construction." *Ex parte* Blankenstein et al., Appeal No. 2007-2872, Application No. 10/116,312 (BPAI Aug. 26, 2008); and *see* Gechter v. Davidson, 116 F.3d 1454 (Fed. Cir. 1997) (emphasis added). In the instant case, other than

paraphrasing Applicants' claim language with annotated citations to FIGS. 6-9 of Fischell, the Examiner provides no finding or other explanation regarding Applicants' claims, Fischell, or the application of Fischell to Applicants' claims.

Furthermore, pursuant to 37 C.F.R. §1.104(b), the Examiner is required to be "complete as to all matters," and 37 C.F.R. §1.104(c)(2) requires that when the reference relied upon "shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable." In this regard, the Examiner generally cites to FIGS. 6-9 of Fischell in the final Office Action in support of the rejections of Claims 1-44. However, simply reprinting the claims and providing a general reference to the figures of Fischell is not "designated as nearly as practicable."

Applicants also submit that the Examiner has failed to satisfy the requirement under MPEP §707.07(f) to provide a clear explanation for rejecting Applicants' arguments made in response to the final Office Action mailed November 4, 2008. Namely, in the Advisory Action mailed March 6, 2009, the Examiner simply states that the "Examiner respectfully disagree [sic] with applicant's remarks." Thus, the Examiner fails to address Applicants' arguments and provide a clear explanation regarding actions taken during prosecution of the present application.

In view of the foregoing, should the Examiner continue to reject the claims as being anticipated by Fischell or on any other ground, Applicants respectfully request that in the Examiner's Answer the Examiner submit on the record specific findings as to the construction being applied to Claims 1-44, an explanation of Fischell being cited against Claims 1-44, and how Fischell discloses the recited features of Claims 1-44.

(a) Independent Claim 1 is Patentable over Fischell

Despite the foregoing, Applicants submit that Fischell fails to teach or suggest the claimed invention. In this regard, Fischell in no way teaches or suggests **a coating coupled to a scaffolding and extending substantially over an area between the struts of the scaffolding**, as recited by independent Claim 1 of the present application. For example, FIG. 3 of the present application illustrates that the coating (100) extends substantially between the legs (32, 36) and connector (40) of the stent scaffolding, which may prevent epithelialization of the stent. In the final Office Action, the Examiner cites to FIGS. 6-9 of Fischell as disclosing the claimed

invention, but Fischell makes no mention of a coating with respect to this embodiment. Rather, FIG. 6 of Fischell is an expanded view of FIG. 5 and simply discloses a stent including strut members and links formed of a highly radiopaque material (see col. 8, lines 41-43 of Fischell). FIGS. 7-9 illustrate different stent configurations affecting the radiopacity thereof, none of which includes a coating. Therefore, Applicants submit that FIGS. 6-9 of Fischell fail to anticipate independent Claim 1.

Furthermore, Applicants note that FIGS. 12A-C of Fischell illustrate a stent having a highly radiopaque coating that is thicker on the end of the strut members (52) as compared to the thickness on either the flex links (54) or the central sets of strut members (56) (see col. 13, lines 8-12 of Fischell). Fischell further discloses that the entire stent may be coated to provide an exterior stent surface that is formed of a single metal, and that the coating may be a radiopaque metal and may be additionally coated with a flexible plastic (see col. 13, lines 19-30 of Fischell). However, Fischell discloses that the coating is only applied to the exterior stent surface and is not applied substantially between the struts. In contrast to the claimed invention, FIGS. 11 and 12A-C of Fischell only depict a stent having a radiopaque coating applied to the stent struts rather than substantially between the struts. Although Fischell also discloses that the stent could be coated with a flexible plastic, Fischell nowhere teaches or suggests that the plastic coating is applied substantially over an area between the struts. In fact, Fischell discloses that an example of an acceptable coating is parylene that is typically applied to a surface using chemical vapor deposition in order to provide a protective barrier and may be suitable for attachment of drugs, which is quite unlike the coating recited in Claim 1 and described in the present application.

Moreover, Claim 1 recites that **the exterior surface of the scaffolding is raised with respect to the coating**, which is also not taught or suggested by Fischell. A stent coated in such a manner may reduce the amount of coating surface area that contacts the target lumen in order to only partially limit cilia function and to not significantly affect mucociliary clearance (see p. 6, lines 5-10 and p. 15, lines 6-12 of the present application). Clearly, the coating of Fischell is directed to an entirely different purpose, including providing radiopacity and corrosion resistance, and is not raised with respect to a coating extending over an area between the struts

especially given that there is no coating between the struts. As such, independent Claim 1 is distinguishable from Fischell for this additional reason.

Therefore, Applicants submit that Fischell fails to teach or suggest independent Claim 1 and that the rejection under 35 U.S.C. §102(e) is overcome. Because the dependent claims include each of the recitations of a respective independent claim, Applicants further submit that the dependent claims are also allowable for at least those reasons discussed above with respect to independent Claim 1.

Although the dependent claims are allowable for at least those reasons discussed above, Applicants respectfully submit that several of the dependent claims are further patentably distinct from Fischell. In fact, the Examiner simply dismisses several of the dependent claims as being anticipated by Fischell without providing any evidence supporting such conclusions. As such, Applicants submit that the Examiner has again failed to satisfy the requirement under MPEP §706 and 37 C.F.R. §1.104, as described above, and has not provided a clear explanation for the rejection of the dependent claims. Therefore, Applicants also request clarification in the Examiner's Answer with respect to the rejection of the dependent claims.

(b) Dependent Claim 2 is Separately Patentable from Fischell

Despite the lack of clarity in the final Office Action regarding the rejection of the dependent claims, Applicants respectfully submit that Fischell does not teach or suggest that the coating is coupled with the scaffolding such that both the struts and the area between the struts are coated, wherein the coating is of sufficient thickness to prevent the medical appliance from becoming epithelialized when installed in the desired portion of the patient's anatomy, as recited by dependent Claim 2. As disclosed in the present application, the stent may be coated to prevent epithelialization of the stent. Preventing epithelialization allows the stent to be removed or repositioned if desired and maintains the patentcy of the stent lumen. Fischell nowhere teaches or suggests that both the stent and the area between the struts are coated in order to prevent epithelialization. At most, Fischell discloses that the struts are coated with a protective layer but does not otherwise teach or suggest that the area between the struts is also coated in order to prevent epithelialization. Thus, Fischell also does not teach or suggest Claim 2.

(c) Dependent Claim 7 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 7 is further patentably distinct from Fischell. Namely, Fischell fails to teach or suggest that at least one strut defines an aperture therethrough (see FIGS. 1-3). In the Office Action, the Examiner simply concludes with reference to Fischell that "the scaffolding is inherently capable of having at least one aperture defines [sic] an eyelet of sufficient diameter to receive suture." Under MPEP §2112, it is the Examiner's burden to provide rationale or evidence demonstrating the inherency of a result or characteristic alleged to be present in the prior art, whether under an anticipation or obviousness rejection. However, the Examiner provides no evidence supporting his assertion, and Applicants submit that Fischell provides no such teaching or suggestion to include an aperture defined in at least one strut. Thus, Claim 7 is further distinct from Fischell.

(d) Dependent Claim 8 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 8 is further patentably distinct from Fischell. Claim 8 recites that the at least one aperture defines an eyelet of sufficient diameter to receive suture. As described above with respect to Claim 7, the Examiner alleges that this particular aspect is "inherent" in light of Fischell despite providing no evidence for doing so. Thus, Applicants submit that Claim 8 is further patentably distinct from Fischell.

(e) Dependent Claim 9 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 9 is further patentably distinct from Fischell. Claim 9 recites that the eyelet diameter is at least 300 μm. As described above with respect to Claim 7, the Examiner alleges that this particular aspect is "inherent" in light of Fischell despite providing no evidence for doing so. Thus, Applicants submit that Claim 9 is further patentably distinct from Fischell.

(f) Dependent Claim 11 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 11 is further patentably distinct from Fischell. Claim 11 recites that the coating is coupled with the medical appliance from the interior surface of the scaffolding outward. For example, the present application discloses on page 15, lines 6-12 that the stent may be coated from the interior of the stent to allow cilia

movement (see also p. 15, line 13 – p. 16, line 4 of the present application for exemplary techniques for coating the stent). The Examiner does not even address Claim 11 in the final Office Action, and Applicants submit that Fischell clearly does not teach or suggest Claim 11.

(g) Dependent Claims 12 and 13 are Separately Patentable from Fischell

Applicants respectfully submit that dependent Claims 12 and 13 are further patentably distinct from Fischell. Claims 12 and 13 recite that the coating is coupled with the medical appliance from the exterior surface of the scaffolding inward. The Examiner does not even address Claims 12 and 13 in the final Office Action, and Applicants submit that Fischell clearly does not teach or suggest Claims 12 and 13.

(h) Dependent Claim 14 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 14 is further patentably distinct from Fischell. Claim 14 recites that the coated struts on the exterior surface of the scaffolding are raised with respect to the coated area between the struts of the medical appliance. The Examiner does not even address Claim 14 in the final Office Action, and Applicants submit that Fischell clearly does not teach or suggest Claim 14.

(i) Dependent Claim 15 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 15 is further patentably distinct from Fischell. Claim 15 recites that the coated strut is raised between 1 Å to 10^6 Å with respect to the coated area between the struts of the medical appliance. As disclosed above, the raised scaffolding with respect to the coating may facilitate cilia movement between the struts and prevent epithelialization (see p. 6, lines 6-12 of the present application). In the final Office Action, the Examiner generally concludes that "the coated strut is raised can be [sic] between 1 .ANG. to 106 .ANG. with respect to the coated region between the struts of the medical appliance." However, the Examiner again provides no evidence or rationale stemming from Fischell that would support such an allegation. Therefore, Applicants submit that Fischell fails to teach or suggest Claim 15.

(j) Dependent Claim 16 is Separately Patentable from Fischell

Applicants respectfully submit that dependent Claim 16 is further patentably distinct from Fischell. Claim 16 recites that the relative extent to which the coated struts are raised with respect to the coated areas between the struts is sufficient to allow cilia function at the cite of implantation. As disclosed above, the raised scaffolding with respect to the coating may facilitate cilia movement between the struts and prevent epithelialization (see p. 6, lines 6-12 of the present application). The Examiner does not even address Claim 16 in the final Office Action, and Applicants submit that Fischell clearly does not teach or suggest Claim 16.

CONCLUSION

For the above reasons, it is submitted that the rejections of the pending claims are erroneous and reversal of the rejections is respectfully requested. A Claims Appendix containing a copy of claims involved in the appeal, an Evidence Appendix, and a Related Proceedings Appendix are attached.

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Claims Appendix.

1. (Previously Presented) A medical appliance for placement within a portion of the anatomy of a patient, the appliance comprising:

a scaffolding, the scaffolding configured to define a substantially cylindrical member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, along the longitudinal extension of the appliance the scaffolding having an interior and an exterior surface comprising struts; and

a coating coupled with the scaffolding such that the exterior surface of the scaffolding is raised with respect to the coating extending substantially over an area between the struts of the scaffolding.

2. (Previously Presented) The medical appliance of claim 1, wherein the coating is coupled with the scaffolding such that both the struts and the area between the struts are coated, the coating of sufficient thickness to prevent the medical appliance from becoming epithelialized when installed in the desired portion of the patient's anatomy.

3. (Original) The medical appliance of claim 2, wherein the coating is substantially hydrophobic.

4. (Original) The medical appliance of claim 2, wherein the coating is substantially hydrophilic.

5. (Original) The medical appliance of claim 3, wherein the coating is hydroscopic.

6. (Original) The medical appliance of claim 4, wherein the coating is substantially hydroscopic.

7. (Original) The medical appliance of claim 1, wherein at least one strut defines an aperture there through.

8. (Original) The medical appliance of claim 7, wherein the at least one aperture defines an eyelet of sufficient diameter to receive suture.

9. (Original) The medical appliance of claim 8, wherein the eyelet diameter is at least 300 μm.

10. (Original) The medical appliance of claim 2, wherein the coating does not inhibit flexing or radial expansion of the medical appliance.

11. (Original) The medical appliance of claim 10, wherein the coating is coupled with the medical appliance from the interior surface of the scaffolding outward.

12. (Original) The medical appliance of claim 11, wherein the coating is coupled with the medical appliance from the exterior surface of the scaffolding inward.

13. (Original) The medical appliance of claim 2, wherein the coating is coupled with the medical appliance from the exterior surface of the scaffolding inward.

14. (Previously Presented) The medical appliance of claim 13, wherein the coated struts on the exterior surface of the scaffolding are raised with respect to the coated area between the struts of the medical appliance.

15. (Previously Presented) The medical appliance of claim 14, wherein the coated strut is raised between 1 Å to 10^6 Å with respect to the coated area between the struts of the medical appliance.

16. (Previously Presented) The medical appliance of claim 14, wherein the relative extent to which the coated struts are raised with respect to the coated areas between the struts is sufficient to allow cilia function at the cite of implantation.

17. (Original) The medical appliance of claim 1, wherein the dimensions of the scaffolding geometry determine torsionality of the medical appliance.

18. (Original) The medical appliance of claim 1, wherein the scaffolding is formed of a memory capable alloy.

19. (Original) The medical appliance of claim 18, wherein the scaffolding is electropolished.

20. (Original) The medical appliance of claim 1, wherein along the longitudinal expanse of the scaffolding the medical appliance further comprise a plurality of flanges that define apertures there through.

21. (Original) The medical appliance of claim 1, further comprising a connector coupled with portions of the geometrical patterns, the connector comprising a crossing member and a plurality of leg members extending from the crossing member.

22. (Original) The medical appliance of claim 21, wherein the connector further comprises a rectangular detent extending from a leg thereof.

23. (Previously Presented) The medical appliance of claim 21, wherein a length of the leg members and an angle at which the legs extend from the crossing member determines the relative flexibility of the medical appliance.

24. (Previously Presented) The medical appliance of claim 23, wherein the angle at which the leg members extend from the crossing member is greater than 90°.

25. (Previously Presented) The medical appliance of claim 24, wherein the medical appliance is relatively rigid.

26. (Previously Presented) The medical appliance of claim 23, wherein the angle at which the leg members extend from the crossing member is 90° or less.

27. (Previously Presented) The medical appliance of claim 26, wherein the medical appliance is relatively flexible.

28. (Previously Presented) The medical appliance of claim 1, further comprising an additional distal end wherein the medical appliance forms a substantially Y-shape.

29. (Previously Presented) The medical appliance of claim 28, wherein the additional distal end comprises scaffolding having at least one strut defining an aperture there through.

30. (Previously Presented) The medical appliance of claim 29, wherein the at least one aperture defines an eyelet of sufficient diameter to receive suture.

31. (Previously Presented) The medical appliance of claim 30, wherein the eyelet diameter is at least 300 μm.

32. (Previously Presented) The medical appliance of claim 28, wherein along a longitudinal axis of the medical appliance and the additional distal end, the scaffolding forms geometrical patterns.

33. (Previously Presented) The medical appliance of claim 32, wherein the scaffolding further comprises a coating coupled with the scaffolding, the coating of sufficient thickness to prevent the medical appliance from becoming epithelialized when installed in the desired portion of the patient's anatomy.

34. (Previously Presented) The medical appliance of claim 33, wherein the dimensions of the scaffolding geometry determine torsionality of the medical appliance.

35. (Previously Presented) The medical appliance of claim 34, wherein the scaffolding is formed of a memory capable alloy.

36. (Previously Presented) The medical appliance of claim 34, wherein the scaffolding is electropolished.

37. (Previously Presented) The medical appliance of claim 33, wherein near the distal and proximal ends of the scaffolding the medical appliance further comprise a plurality of flanges that define apertures there through.

38. (Previously Presented) The medical appliance of claim 28, further comprising a connector member coupled with portions of the geometrical patterns, the connector comprising a crossing member and a plurality of leg members extending from the crossing member.

39. (Previously Presented) The medical appliance of claim 38, wherein the connector further comprises a rectangular detent extending from a leg thereof.

40. (Previously Presented) The medical appliance of claim 38, wherein a length of the leg members or a degree of an angle at which the legs extend from the crossing member positively contributes to the relative flexibility of the medical appliance.

41. (Previously Presented) The medical appliance of claim 40, wherein the angle at which the leg members extend from the crossing member is greater than 90°.

42. (Previously Presented) The medical appliance of claim 41, wherein the medical appliance is relatively rigid.

43. (Previously Presented) The medical appliance of claim 40, wherein the angle at which the leg members extend from the crossing member is 90° or less.

44. (Previously Presented) The medical appliance of claim 43, wherein the medical appliance is relatively flexible.

45. (Withdrawn) A method of coating a medical appliance, comprising the steps of:

providing a mold having an internal and an external diameter;

providing a medical appliance comprising a scaffolding, the scaffolding configured to define a substantially cylindrical member having a distal end and a proximal end and extending longitudinally there between, forming a lumen there through, along the longitudinal extension of the appliance the scaffolding having an interior and an exterior surface;

inserting the medical appliance into the internal diameter of the mold;

applying a polymer to the interior surface of the medical appliance; and

annealing the polymer to the stent by applying heat to the polymer.

46. (Withdrawn) The method of claim 45, further comprising the step of applying a polymer to the exterior surface of the medical appliance.

47. (Withdrawn) The method of claim 45, wherein providing comprises providing a medical appliance further comprising an additional distal end wherein the medical appliance forms a substantially Y-shape.

48. (Withdrawn) The method of claim 45, wherein applying comprises applying the polymer such that the exterior surface of the scaffolding is raised with respect to the polymer applied over at least a portion of an area between the scaffolding.

49. (Withdrawn). The method of claim 45, further comprising spraying the medical appliance with a polymer prior to applying the polymer to the interior surface of the medical appliance.

Evidence Appendix.

None.

Related Proceedings Appendix.

None.